II. REMARKS

Reconsideration of the present application in view of the following remarks is respectfully requested.

A. Status of the claims

Claims 8-11, 13, 14, 16, 20, 22-24, 29, 30, 32-38 and 40-49 are pending. Claims 8 and 20 have been amended. Support for the amendments can be found in the original specification as filed, e.g., on page 17, line 19; page 19, line 17; and page 19, line 25. Applicants respectfully submit that no new matter has been added by virtue of the present amendment.

B. Rejection under 35 U.S.C. § 103

Claims 8-11, 13, 14, 16, 20-24, 29, 30, 32-38, and 40-49 were rejected under 35 U.S.C. § 103 (a) over U.S. 4,910,205 to Kogan et al. ("the Kogan patent") in view of U.S. 5,968,547 to Reder et al. ("the Reder patent"). With respect to the Kogan patent, the Examiner stated that Kogan does not teach "a transdermal delivery device including polymer, solvents and softening agents in the transdermal delivery system."

Initially, Applicants note that independent claims 8 and 20 of the present application have been amended to recite that the recited transdermal delivery system comprises "(i) an active agent consisting of loratadine or a pharmaceutically acceptable salt thereof, (ii) a polymer, (iii) a softening agent and (iv) a solvent". Applicants also note that independent claim 46 includes the limitation that the reservoir layer of the recited transdermal delivery system consists essentially of 20 to 90% by weight of a polymeric matrix, 0.1 to 30% by weight of a softening agent, 0.1 to 20% by weight of loratadine base or of a pharmaceutically acceptable salt thereof and 0.1 to 30% by weight of a solvent for the loratadine or salt thereof."

Applicants respectfully submit that the presently claimed invention is not obvious over the Kogan patent in view of the Reder patent. As acknowledged by the Examiner, the Kogan patent does not teach "a transdermal delivery device including polymer,

solvents and softening agents in the transdermal delivery system." Applicants further submit that one skilled in the art would not be motivated to combine the Reder patent with the Kogan patent as each reference is directed to different utilities.

In support of this position, Applicants note that the subject matter of the Kogan patent is limited to transdermal delivery devices of loratadine for the treatment of allergic reactions (see Abstract of the Kogan patent). In contrast, the subject matter of the Reder patent is limited to transdermal delivery devices of buprenorphine for the treatment of pain or opioid addiction (see Abstract and column 3, line 17 of the Reder patent).

Applicants respectfully submit that one skilled in the art would not look to a reference directed to pain and opioid addiction in order to modify a dosage form to be utilized for treating allergic reactions. Further, one skilled in the art would not be motivated to look to a reference limited to an opioid (i.e., buprenorphine), in order to modify a dosage form containing an antihistamine (i.e., loratadine).

Further, Applicants submit that the disclosure of the Reder patent is specifically directed to buprenorphine and does not teach or suggest that the transdermal formulations and methods described therein are suitable for use with any agent other than buprenorphine.

Accordingly, the present claims are not obvious over the Kogan patent in view of the Reder patent as one skilled in the art would not be motivated to combine the references.

Further, even if the Kogan patent and the Reder patent were combined (a position vehemently denied by the Applicants), one skilled in the art would not arrive at the presently claimed invention.

Initially, independent claims 8, 20 and 46 all recite that the active agent is solely limited to loratadine, by virtue of the closed ended terminology recited in the respective

claims. Applicants submit that the formulations and methods of the Reder patent all contain buprenorphione as a necessary ingredient. Therefore, looking as the Reder reference as a whole, it is impermissible for the Examiner to "pick and choose" specific ingredients from the Reder patent to combine with the Kogan patent, without considering the entire teachings of the reference (See *Smith Kline Diagnostics, Inc. v. Helena Laboratories Corporation*, 859 F. 2d 878, 887 (Fed. Cir. 1988)). Therefore, a formulation prepared in accordance with teachings of the Reder reference must contain buprenorphine, which is excluded from the present claims. The Examiner is reminded that that "[a] prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention." (Emphasis included) *W.L. Gore and Associates, Inc. v. Garlock, Inc.*, 721 F. 2d 1540, 220 USPQ 303 (Fed. Cir. 1983).

Applicants further submit that the neither the Kogan patent nor the Reder patent teach or suggest the specific delivery profiles of loratidine as claimed in independent claims 8, 20 and 46. Therefore, a combination of the references cannot obviate independent claims 8, 20, and 46 of the present invention.

With respect to the Kogan patent, the Examiner stated the following:

The claimed delivery rates are met by the reference because the claimed rates are broadened by the term "about" and inclusive of the rates disclosed by the prior art. The prior art rate of delivery is 0.66 mg/15 cm^2/day, i.e. 44 $\mu g/cm^2$/day, and as claimed is about 16.2 44 $\mu g/cm^2$/day.

In response, Applicants submit that one skilled in the art would not consider that the term "about" broadens the recited rate of 16.2 $\mu g/cm^2$/hr to 44 $\mu g/cm^2$/day, which is about 270% higher than the recited value. Further, the Reder reference is specifically limited to buprenorphine and therefore does not teach or suggest delivery parameters for loratadine. Accordingly, Applicants respectfully submit that the Examiner's rejection is based on the impermissible hindsight reasoning afforded by the present invention.

With respect to independent claim 46, Applicants submit that the Kogan patent states that a surprising result was provided by a loratadine transdermal device which contains a combination of a volatile solvent, an essential oil and a fatty acid ester (see the Kogan patent, col. 1, lines 54-59). Therefore, a combination of the Kogan patent and the Reder patent would necessarily result in a transdermal delivery device which contains an essential oil as one skilled in the art would lack motivation to formulate a device that does not include an essential oil. Therefore, the combination of references cited by the Examiner cannot render obvious a transdermal delivery system comprising "a reservoir layer consisting essentially of 20 to 90% by weight of a polymeric matrix, 0.1 to 30% by weight of a softening agent, 0.1 to 20% by weight of loratadine base or of a pharmaceutically acceptable salt thereof and 0.1 to 30% by weight of a solvent for the loratadine or salt thereof," as recited in claim 46 and the claims dependent thereon (emphasis added).

The Examiner further stated that the recitation of the in-vitro Valia-Chien test "does not impart patentability" to the claims. Applicants note that "[a] functional limitation must be evaluated and considered, just like any other limitation of the claim, for what it fairly conveys to a person of ordinary skill in the pertinent art in the context in which it is used." MPEP 2173.05(g), Eighth Edition, Revision 2. Accordingly, Applicants submit that the specific release rates recited in the present claims should be "evaluated and considered, just like any other limitation of the claim" in determining patentability of the present claims. See MPEP 2173.05(g), Eighth Edition, Revision 2.

III. CONCLUSION

An early and favorable action is earnestly solicited. The Examiner is invited to contact the undersigned by telephone if a telephone interview would advance prosecution of the present application.

Respectfully submitted,
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